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(54) Ostomy coupling

(57) An ostomy coupling has first and second coupling elements 10, 30 of which one has a flange carrying a first annular wall 14 upstanding therefrom. The free end of this wall has a radially outwardly extending sealing and latching member 16. The second coupling element 30 has an annular wall 34 (herein called a second annular wall) surrounding a stomal orifice and, radially outwardly therefrom, a third annular wall 36 of lesser height than the second annular wall. The third wall carries an inwardly extending projection 37 to cooperate with the sealing and latching member.

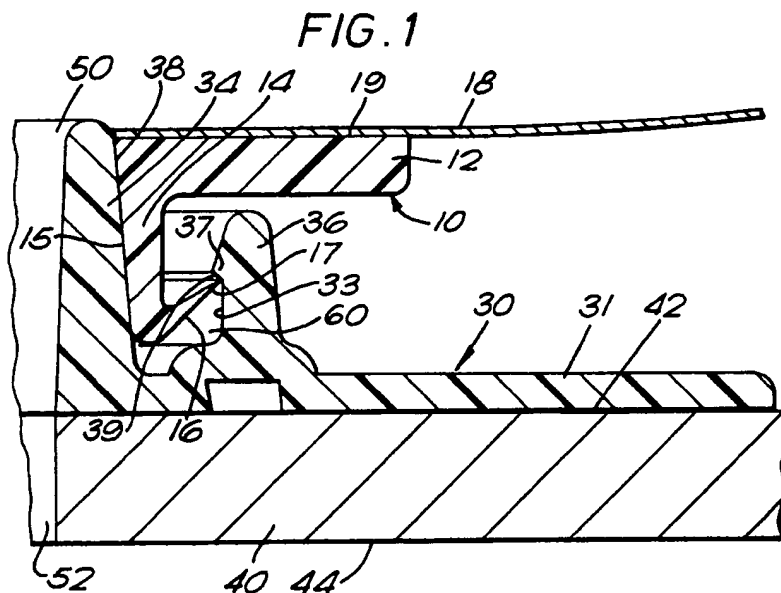




FIG. 3

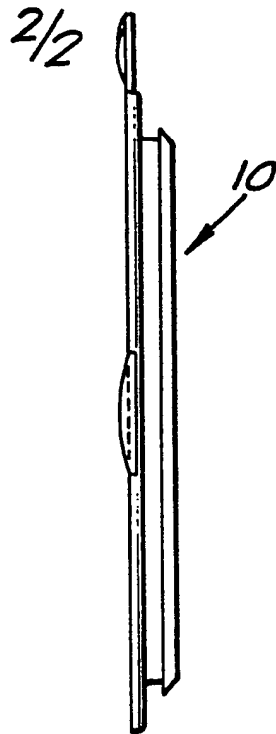


FIG. 5

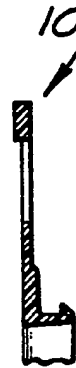


FIG. 4

FIG. 6

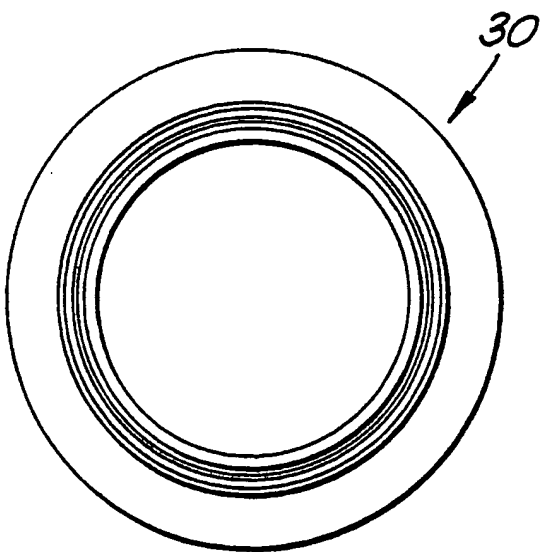


FIG. 7



OSTOMY COUPLING

This invention relates to an ostomy coupling.

There have been many attempts to devise ostomy couplings, and one particular design has been widely successful, see U.K. Patent No. 1 571 657. It would be desirable, however, if there existed a low profile system with a light fitting pressure and yet a high latch release pressure. By 'low profile' in this context is meant a coupling which stands out from the body of the wearer by only a small distance. This is desirable because wearers of ostomy appliances do not wish them to give rise to a bulge under clothing and, ideally, they should not be noticeable even under light sports clothing.

According to the present invention, there is provided an ostomy coupling comprising first and second coupling elements of which one has a flange carrying a first annular wall upstanding therefrom, the free end of this wall having a radially outwardly extending sealing and latching member, the second coupling element having an annular wall (herein called a second annular wall) surrounding a stomal orifice and, radially outwardly therefrom, a third annular wall of lesser height than the second annular wall and carrying an inwardly extending projection to cooperate with the sealing and latching member.

In accordance with a preferred embodiment of the invention, the inner surface of the first annular wall and the outer surface of the second annular wall are tapered in a complementary manner. For example these surfaces are preferably both shaped as a frustum of a cone with a cone angle of from 6 to 14 degrees, preferably 8-12 degrees, and desirably 10 degrees. In other words, the angle of the outer surface of the second annular wall to the axis of the coupling, measured in a radial plane, may be from 3 to 7 degrees, preferably 4 to 6 degrees and most preferably 5 degrees. The main purposes of this taper are to achieve good sealing and to ensure the proper relative orientation between the tip of the sealing and latching member and its confronting projection on the third annular wall, when the elements are in their mutually coupled condition.

In use, due to the direction in which the sealing and latching member extends, coupling of the elements is achieved with only a small applied force since the tip of the latching and scaling member slides smoothly past a surface of the third annular wall. On the other hand, to uncouple, a greater pulling force must be applied in order to bend and deform the sealing and latching member so that it can be pulled past the projection. Best results have been achieved, from the point of view of securing a light fitting but high latch release pressure by providing the projection with a surface located at from 25 to 35, preferably about 30 degrees to the horizontal, assuming the coupling element to be located with the major surface of its flange horizontal.

In a preferred embodiment of the invention, the first coupling element is the bag-side coupling element and is advantageously attached to the wall of an ostomy bag, and the second coupling element is the body-side coupling element which in normal use is fixed to one side of a pad of medical grade adhesive having protective and curative properties. This pad may have a central stomal orifice or may have a central portion which can be removed to provide such an orifice. As is well known in ostomy couplings, such medical grade adhesive pads may have paper layers carrying a diagram to assist the user in cutting out the central portion to provide a stomal orifice, if a stomal orifice is not already present.

One illustrative example of the present invention will be better understood from the following particular description given with reference to the drawings in which:-

Figure 1 is a cross-section in an axial plane, taken through the rotational axis of the coupling, showing half of one example of ostomy coupling according to the invention on a larger scale than used in Figs 2-7;

Figures 2, 3, 4 and 5 are respectively front view, scrap section on line A-A, side view, and scrap section on centre line through the belt tab, of one example of a first (bag-side) coupling element; and

Figures 6 and 7 are respectively a front view and a side view of one example of a second (body-side) coupling element.

The particular embodiment of the invention illustrated is a two-part coupling by which an ostomy bag or pouch can be connected to a pad by using a light fitting pressure, but which requires a relatively heavier separating force to detach a filled bag with its bag-side coupling element from the body-side coupling element which remains on the medical grade adhesive pad. Two-part ostomy couplings are already known, see for example British Patents Nos. 1 571 657 and 1 568 860.

The present invention adopts a two-stage approach to satisfactory sealing between the two coupling elements, involving the cooperation of substantially conically tapered surfaces on the body-side and bag-side coupling elements and the cooperation of a resilient plastic latching and sealing member on one element with a confronting projecting surface of special shape upon the other coupling elements.

The illustrated bag-side coupling element 10 comprises a substantially circular flange 12 having a flat surface 19 over which an ostomy bag wall 18 is secured by welding, adhesive or in any other convenient manner. Integral with the flange 12 is a first annular wall 14 which has a tapered inner wall surface 15 and, at its end further from the flange 12, has an integral sealing and latching member 16. This member 16 extends around the entire periphery of the first coupling element. The element is preferably made of a synthetic plastics material, for example ethylene vinyl acetate polymer. That known by the grade number UL00209 and available from Esso Petroleum Company Limited is an example of a suitable material. Of course other materials may be used.

A second body-side coupling element 30 includes a generally circular flange 31 surrounding a stomal orifice 50 and having a surface which may be joined a pad 40 of a medical grade adhesive by, for example, an adhesive layer 42. The second coupling element may be joined to the medical grade adhesive pad by other means if desired. The medical grade adhesive pad has a surface 44 which is intended for direct application to the peristomal area of the skin of the wearer. Suitable material for the pad 40 is that known as "Stomahesive" (Registered Trademark) or that known as

"Duoderm" (Trademark) available from ConvaTec Limited, Hounslow, Middlesex. Other suitable medical grade adhesive materials are available and may be employed instead. There is a stomal orifice 52 in the pad 40. Alternatively, the pad may carry a label marking the area of the centre of the pad which is to be cut out in order to produce a suitable stomal orifice. In use the intending wearer cuts out a central generally circular portion before application of the pad to the peristomal skin area. The second coupling element 30 may advantageously be made of low density polyethylene, e.g. Esso Grade 600 BA, but other suitable materials are available and may be used instead.

The second coupling element includes a radially inner annular wall 34 and a radially outer annular wall 36. The wall 34 has a substantially conically tapered outer surface 38. A taper of this surface is arranged to be complementary to that of the surface 15 of the element 12. The height of the wall 34 is greater than the height of the wall 14 of the element 12. The shape of the inner wall surface of the wall 34 is not of critical importance except that it is desirable for it to be as smooth as possible so not offering any crevices or impediments to exit of discharged body wastes. These pass from the stoma of the wearer into the bag, one wall 18 of which only is shown.

The outer annular wall 36 is of lesser height than the wall 34 and its inner surface has a projection 37 which extends inwardly forming a "nose" at a precisely defined height. This projection 37 extends completely around the wall 36 and is bounded on its lower side as seen in the drawing by an angled annular surface 39. The position of this projection and the position of the sealing and latching member 16 and the dimensions of the first and second coupling elements are chosen so that in the normal mutually coupled position of the two parts the tip of the sealing and latching member 16 takes up a position in contact with the angled join between the surface 39 and the lower part 33 of the radially inner wall surface of the wall 36. The effect of this arrangement is that the tapered interfitting engagement between surfaces 15 and 38 provides an effective seal and any liquid which manages

to find its way through this seal is retained in the volume indicated 60 in the drawing and is prevented from passing to the exterior because of the resilient engagement between the sealing and latching member 16 and the confronting portion of the wall 36. The angled surface 39 and the direction in which the sealing and latching member 16 extends cooperate to provide a resistance to separation of the two cooperating coupling elements. As can be seen, in order to separate the two elements, a force must be applied sufficient to bend over the tip portion 17 of the sealing and latching member 16.

The preferred cone angle for the interfitting engaging surfaces 15 and 38 is 10 degree cone angle, that is to say, a 5 degree angle to the central axis of rotation of the coupling element. However, any cone angle between about 4 degrees and about 18 degrees may be suitable, with a more preferred range being 8-12 degrees.

While there have been suggestions before to utilize a plastics sealing lip to make a mechanical engagement with some other coupling part, in order to hold two coupling parts together, these have not generally speaking been satisfactory in practice. In contrast to this, the present invention by its cooperation between a carefully defined and specified conical tapering engagement between two coupling elements in addition to the sealing and latching member 16 cooperating with a suitable confronting surface on the other coupling element yields an ostomy coupling having the advantage, hitherto not achieved to the degree achieved by the particular embodiment of the present invention, namely that the fitting or coupling pressure is light whereas the separating force is relatively heavy. This promotes a feeling of security in the user and yet makes the coupling easy to use while still having good sealing characteristics and a low overall height so making the coupling relatively unnoticeable beneath clothing.



## CLAIMS

1. An ostomy coupling comprising first and second coupling elements of which one has a flange carrying a first annular wall upstanding therefrom, the free end of this wall having a radially outwardly extending sealing and latching member, the second coupling element having an annular wall (herein called a second annular wall) surrounding a stomal orifice and, radially outwardly therefrom, a third annular wall of lesser height than the second annular wall and carrying an inwardly extending projection to cooperate with the sealing and latching member.
2. A coupling according to claim 1 in which the inner surface of the first annular wall and the outer surface of the second annular wall are tapered in a complementary manner.
3. A coupling according to claim 2 in which the said surfaces are both shaped as a frustum of a cone with a cone angle of from  $6^{\circ}$  to  $14^{\circ}$ .
4. A coupling according to claim 3 in which the cone angle is from  $8-12^{\circ}$  and preferably is substantially  $10^{\circ}$ .
5. A coupling according to any preceding claim in which the outwardly extending sealing and latching member is integral with the remainder of the first coupling element and its free end is disposed in contact with the base of a recess in the outer annular wall of the second coupling element.
6. A coupling according to claim 5 in which the recess is in part defined by a peripheral annular surface angled to the plane of the flange of the second coupling element at an angle of approximately  $45^{\circ}$ .
7. An ostomy coupling substantially as hereinbefore described and illustrated.
8. All novel aspects of the invention disclosed herein.

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